PERRIGO

November 3, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Proposed Rule
180 Day Generic Drug Exclusivity for Abbreviated New Drug Applications
[Docket No. 85N-0214]

Dear Sir or Madam:

Perrigo Company respectfully submits these comments in response to the Food and Drug Administration's Proposed Rule - 180 Day Generic Drug Exclusivity for Abbreviated New Drug Applications [Docket No. 85N-0214].

Perrigo is the nation's largest private-label manufacturer of over-the-counter drug products, serving numerous chain drugstores and supermarkets. Most of these OTC products are marketed under OTC monographs. Many of Perrigo's drug products are covered by approved abbreviated new drug applications (ANDA's). Future ANDA submissions will be affected by this rule when finalized.

Following are comments on the general areas covered the proposed rule:

Substantially Complete Applications – FDA should not impose a new standard for determining when an ANDA is substantially complete. The determination of completeness for purposes of exclusivity qualification should be made at the time of original filing. There should not be an opportunity to retroactively change that determination based on requirements of which the applicant may have had no reason to be aware and could not have anticipated at the time of product development and application filing.

Triggering Period – Perrigo supports the concept of the triggering period as a means of preventing delays to the prompt entry of generics into the market. Although there is cause for concern over the outcome or effect of future court rulings on the FDA proposal, we believe that it is preferable to have a proposal such as this to allow the Agency to move forward to remedy the current situation.

Shared First Filer Status – Perrigo supports FDA taking reasonable steps to assign exclusivity only to the first to file applicant. We do not support sharing of this exclusivity. Further, if a true exclusivity cannot be awarded to the first filer, no exclusivity should be awarded to any applicant when more than one ANDA is received on the same day.

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Rolling Exclusivity – Perrigo opposes an allowance for Rolling Exclusivity. We feel that this position promotes the greatest probability of generic competition in the marketplace at the earliest date and best fulfills the intent of Congress to reward the first ANDA filed with a paragraph IV certification.

Only One 30-Month Stay – Perrigo urges FDA to adopt a regulation that would result in only a single 30 month stay being imposed on all paragraph IV applicants who are sued for patent infringement. Thus if the first applicant is sued within 45 days of its paragraph IV certification and subsequent applicants are also sued, the subsequent applicants would only be subject to whatever time remains on the first applicants 30 month stay. This will promote earliest entry of generic products.

Transfer of Exclusivity – Perrigo opposes the prohibition of any transfer of exclusivity to a particular subsequent applicant until the exclusivity period has been started by a triggering event. Such transfers should be allowed during any time that an applicant is eligible for the exclusivity, even if the period has not yet begun.

Decision on First Patent – The exclusivity period should begin at the decision of the first of several patents if beginning the period at that time would allow other generics to enter the market at an earlier date (i.e., that patent would be relevant to the marketing of the product). If the first patent is not relevant to the marketing of the drug, then the exclusivity period should not be triggered until a decision on the first relevant patent. Perrigo would generally support the interpretation which allows the fastest market entry of generic products.

Dismissal of Declaratory Judgement – We agree with the Agency's decision to recognize that the statute requires the start of the first applicant's 180-day exclusivity period upon a court decision in a declaratory judgement action brought by a subsequent applicant against the patent owner. However, we disagree with the Agency's refusal to recognize that a "case or controversy" dismissal of such a lawsuit, based upon a finding that the generic applicant has no reasonable apprehension of being sued for infringement if it were to begin marketing its version of the drug, does not constitute a "court decision" for purposes of triggering the exclusivity period.

Effective Date of Changes – Perrigo agrees that any changes should only apply to ANDAs filed after the finalization of any new regulatory interpretations.

Perrigo appreciates the opportunity to submit these comments. If you have any questions, please feel free to call me at 616-673-9745.

Sincerely,

PERRIGO COMPANY

Brian Schuster
Manager, ANDA Submissions

REGULATORY AFFAIRS DEPARTMENT
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FACSIMILE TRANSMISSION

DATE: *November 3, 1999*

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MESSAGE: Attached are comments to the FDA Proposed Rule -180 Day Generic Drug Exclusivity for Abbreviated New Drug Applications **[Docket No. 85N-0214]**

Please call (616) 673-9745 if there are transmission problems.